

### **REMARKS**

With entry of the present amendment, claims 1 to 7 and 9 are pending. Claims 1, 7, and 9 are amended. Claims 8, 10, and 11 have been cancelled. No claims have been added. No new matter is believed to be presented by the foregoing amendments.

Claim 1 was amended to incorporate the recitations of now-cancelled claim 8 and mirrors the scope of claim 8, which the Examiner has deemed allowable. Claim 7 has been amended to more particularly define the present invention. Support for the amendment to claim 7 is in the application at page 2, lines 20 and 21. Claim 9, which was dependent on now-cancelled claim 8, has been amended to be dependent from claim 1 which now incorporates the recitations of claim 8 and mirrors the scope thereof.

The present amendment has been made to place the claims into a form for allowance. As such, entry of this amendment and reconsideration of the claims, as amended and in view of the following remarks, is requested.

### **The Section 112 Rejections**

Claims 1 to 7 were rejected by the Examiner because allegedly the specification supports only embodiments of the invention which require the use, in step (d) of the process defined, of a denaturing agent in a non-denaturing concentration. Without acquiescing to the Examiner's rejection, applicants note that this aspect of the Section 112 rejection of claims 1 to 7 has been overcome by the present amendment to the claims. Claim 1, from which claims 2 to 7 depend, has been amended to incorporate the recitations of now-cancelled claim 8, which specifies the use, in step (d), of a denaturing agent in a non-denaturing concentration and which the Examiner has already deemed to be allowable.

Claim 7 was also rejected because the specification allegedly does not support the performance of steps (c) and (d) at a specific pH range of between pH 8 and 9 unless a potassium phosphate buffer is used. Without acquiescing in the Examiner's rejection, applicants note that this rejection has been overcome by the present amendment to claim 7. Claim 7 now specifies the use of a potassium phosphate buffer solution in steps (c) and (d).

Claim 9, while reciting the use of a denaturing agent in step (d), was rejected because a method having the particular combination wherein guanidinium hydrochloride is used in step (c) and arginine is used in step (d) is allegedly not contemplated. Applicants respectfully traverse this rejection. This is plainly not the case since the specification, at page 4, line 17 to 26, describes an embodiment of the invention in which an isolated inclusion body is solubilized using a solution containing, as a denaturing agent, guanidinium hydrochloride or urea, and thereafter renaturing the NK4 polypeptide by dissolving the resulting solubilisate in a solution comprising, as a denaturing agent, guanidinium hydrochloride, urea, or arginine. Furthermore, Example 2 specifically describes an embodiment in which the solution used to solubilize the isolated inclusion body comprises guanidinium hydrochloride and the solution used to renature the NK4 polypeptide comprises arginine. As such, it is abundantly clear that it is not the case that a method comprising the use of guanidinium hydrochloride in the solution of step (c) and the use of arginine in step (d) is not contemplated. The Examiner's rejection, therefore, is respectfully traversed.

Without acquiescing in the Examiner's rejection of claims 10 and 11, applicants submit that the rejection with respect to those claims has been rendered moot by the cancellation of those claims.

### **The Objection to Claim 8**

The Examiner advised that subject matter of claim 8 is allowable but that the claim is objected to because it is dependent from a rejected base claim. This objection has been overcome by the present amendment in which independent claim 1, from which claim 8 depended, has been amended to incorporate the recitations of claim 8.

**CONCLUSION**

The foregoing amendment is fully responsive to the Final Office Action issued December 4, 2008. Applicants submit that claims 1 to 7 and 9 are allowable. Early and favorable consideration is earnestly solicited.

If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney is respectfully solicited.

Applicants believe that no fee is due with this communication. However, should the Patent Office determine that a fee is owed, or a credit is due to applicant, the Patent Office is hereby authorized to charge any required fees, including any extension of time and/or excess claim fees, or credit any overpayment, to applicant's Deposit Account 08-2525 as appropriate.

Respectfully submitted,

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